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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/604,158 06/27/00 BESETTE

S 45112-085

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HM12/0126

EXAMINER

PATTEN, P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/604,158	Applicant(s) Bessette, S.
	Examiner Patricia Patten	Group Art Unit 1651

Responsive to communication(s) filed on _____

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1-12 _____ is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-12 _____ is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

... SEE OFFICE ACTION ON THE FOLLOWING PAGES ...

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DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

The Specification is not clear as to the meaning of the initials 'PBO.' It is thought that 'PBO' means 'piperonyl butoxide' however, this is not clear. An insertion relating the term 'PBO' with 'piperonyl butoxide' is recommended for clarification.

Also unclear are the terms 'Microcel E', 'Hi Sil 233', 'DE' and 'S-1080' found in Example

2. Clarification within the Specification is necessary.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

Claims 7, 10 and 12 are rejected under 35 U.S.C. 112, 1st paragraph, because the specification, while being enabling for a composition and/or method for controlling dust mites,

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with a combination of thymol, BA or PEP with PBO acting as a synergist, does not reasonably provide enablement for a combination of any of the plant oils listed in Claim 3 with PBO acting as a synergist. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

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In the instant case, Applicants have demonstrated that combinations of specific plant oils such as thymol, benzyl alcohol and phenethyl propionate act synergistically in combination with piperonyl butoxide (PBO). Synergism, which is predicated on an unexpected result, is a highly unpredictable, rare phenomenon. Applicants have not provided data with regard to any other plant oils such as carvacrol or eugenol which would exhibit a synergistic effect when combined with PBO.

There is only speculation set forth in the specification regarding the applicability with regard to the other claimed species of plant oils and/or derivatives which would perform synergistically with PBO as effectively as those which were actually shown in the specification to possess a synergistic effect. Thus, the effect of a combination of any other plant oil and/or derivative along with PBO would be **highly uncertain**.

With regard to the other members which make up the markush groups of the Instantly claimed invention, there is no guidance or direction presented to direct one to determine other combinations of substances would work, aside from the combinations discussed *supra*, in the broadly claimed invention which is a complex and unpredictable art.

Thus, in order for one of ordinary skill in the art to ascertain what other combinations of plant oils and/or derivatives in combination with PBO would perform within the scope of the

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Instant invention would require a substantial inventive contribution entailing tedious amounts of trial and error experimentation.

With respect to the adequacy of disclosure that a claimed genus possesses an asserted utility, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if it would be deemed likely by one skilled in the art, in view of contemporary knowledge in the art, that the claimed genus would possess the asserted utility. In re Oppenauer, 31 CCPA 1248, 143 F.2d 974, 62 USPQ 297; In re Cavallito et al., 48 CCPA 711, 282F.2d 357, 127 USPQ 202. For both adequate disclosure and/or enablement requires representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope of a claim possess the alleged utility and additionally demonstrate that applicant had possession of the full scope of the claimed invention. See In re Riat et al. CCPA 1964 327 F2d 685, 140 USPQ 471; In re Barr et al. CCPA 1971 444 F2d 349, 151 USPQ 724, for enablement and for disclosure see Court of Appeals for the Federal Circuit decision, The Regents of the University of California v. Eli Lilly and Company which can be found at the Federal Circuit web site, www.fedcir.gov as file 96-1175.

To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a **reasonable expectation** that any one material embodiment of the claimed invention would be more likely than not to function in the

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manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are **more likely to work than not** without actually making and testing them then the instant application does not support the breadth of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12 all recite the term ‘plant essential oil or derivatives.’ The term ‘derivatives’ in the instant case is indefinite in that the term ‘derivatives’ is not clearly defined. A derivative of a plant oil may be a myriad of compounds which are outside of the scope of the present invention. A ‘derivative’ of a plant oil may simply be carbon which would not work commensurate in scope with the claimed invention. Correction is necessary.

Claims 3, 6 and 9 are improper markush groups. Claims 3, 6 and 9 incorporate plant oils such as eugenol with compounds such as dipropylene glycol and 1-phenyl ethyl alcohol. The compounds are different with respect to structure and function, and thus, it is suggested that the

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compounds which are plant oils be placed in a different group (claim) than those compounds which are not plant oils such as dipropylene glycol and benzyl alcohol for example.

Claims 7-10 and 12 either recite, or are dependant upon a claim which recites 'with a synergist.' Although PBO was shown in the specification to be synergistic with thymol, BA and PEP respectively, it is not known what other synergists the claim is referring to. Although the claims are read in light of the Specification, the meets and bounds of the term 'synergist' in this respect are not delineated, and hence, confusing. What other synergists besides piperonyl butoxide would work commensurate in scope with the claimed invention? Clarification is necessary.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubota et al (JP 04091003-A). Claims 1-6 are drawn to a pesticidal composition for the control of house dust

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mites comprising a plant essential oil admixed with a carrier. Claims are further drawn to specific oils such as eugenol, thymol, vanillin or menthol for example.

Kubota et al. (JP 04091003-A) disclosed that eugenol was an effective dust mite (Acaridae) controlling agent (Abstract). Kubota et al. further taught that the eugenol could have been admixed with a carrier, and used as an emulsion, powder, dust, aerosol, fumigant or bait in order to treat areas of infestation (Abstract).

Thus, Kubota et al. clearly anticipated the claimed invention

Furthermore, all of the compositions recited in Claim 3 are all well known compositions in the art (art was not provided for all of the distinct compounds). The language ‘for the control of dust mites’ is merely an intended use for all of the already known compositions of Claim 3:

“Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established.” *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Bessette et al. (US 6,004,569). Claims 1-6 are drawn to a pesticidal composition for the control of dust mites comprising a plant oil admixed with a carrier.

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Bessette et al. (US 6,004,569) disclosed a pesticidal composition which contained ingredients such as plant oils for the control of insects, arachnids and larvae (Abstract). Bessette et al. specifically disclosed that compounds such as eugenol, carvacrol, thymol and citronellal displayed toxicity against insects (please see Table 9, Col.11). Further, Bessette et al. proposed administration of the effective ingredients with carriers such as powders, dust and aerosols (Please see Claims 8-11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bassette et al. (US 6,004,569). Claims 1-6 and 11 are drawn to a pesticidal composition for the control of dust mites comprising a plant oil admixed with a carrier and a method for controlling dust mites by use of such a composition

The teachings of Bassette et al. (US 6,004,569) do not disclose that Bassette et al. did not specifically discuss where the composition could have been effective toward dust mites.

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Bassette et al. disclosed that the compositions of their invention would have been effective towards insects, arachnids and larvae as well as their natural habitat (Abstract). Because the composition disclosed by Bassette et al. were known to have acted as agonists or antagonists on the octopamine receptor sites of insects, one of ordinary skill in the art would have reasonably concluded that since dust mites were insects, that if dust mite octopamine receptors were blocked from the compounds such as thymol or carvacrol for example, that the dust mites would also have perished when exposed to such compounds. One of ordinary skill in the art would have had a reasonable expectation that the compounds disclosed by Bassette et al. would have worked effectively on dust mites considering dust mites are insects and therefore would have reacted similarly to the compounds disclosed by Bassette et al. as being effective pesticides.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 7-10 and 12 are free of the art, however, were rejected under 35 U.S.C. 112 1st paragraph (*supra*)

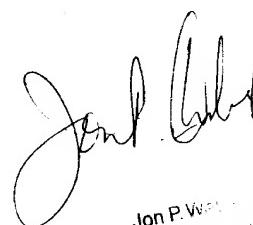
No Claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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